

K121699

SECTION 12 510(k) Summary

JUN 22 2012

11.1. Sponsor: Siemens Medical Solutions USA, Inc.,
Ultrasound Division
685 East Middlefield Road
Mountain View, California 94043

11.2. Contact Person: Shelly Pearce
Title: Regulatory Affairs Specialist
Telephone: (650) 694 5988
Fax: (650) 694 5580

11.3. Submission Date: May 15, 2012

11.4. Device Name: ACUSON X300™ Diagnostic Ultrasound System
SONOVISTA X300 Diagnostic Ultrasound System
ACUSON X300™ Diagnostic Ultrasound System, premium edition
(K090276, K093531)

11.5. Common Name: Diagnostic Ultrasound System with Accessories

11.6. Classification:

Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX
Diagnostic Intravascular Catheter	FR # 870.1200	Product Code 74-DQO

A. Legally Marketed Predicate Devices

The Siemens ACUSON X300 Diagnostic Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to the current product that is already cleared for USA distribution under the following 510(k) PreMarket Notification number:

- K090276, K093531, ACUSON X300™ Diagnostic Ultrasound System, SONOVISTA X300 Diagnostic Ultrasound System, ACUSON X300™ Diagnostic Ultrasound System, premium edition
- K113179, ACUSON SC2000™ Diagnostic Ultrasound System
- K101091, ZONARE z.one Ultra Ultrasound System
- K113690, GE LOGIQ i, LOGIQ e, Vivid e
- K014206, GE LogiqBook XP
- K101757, Sonosite M-turbo

B. Device Description:

The Siemens ACUSON X300 Diagnostic Ultrasound System is a multi-purpose mobile, software controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical

indices related to potential bio-effect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging and 3D Imaging, or Harmonic Imaging and 4D imaging on a Flat Panel Display.

C. Intended Use

The Siemens Acuson X300 ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Neonatal/Adult Cephalic, Cardiac, Transesophageal, Pelvic, Transcranial, OB/GYN, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

D. Substantial Equivalence

The submission device is substantially equivalent to the predicate with regard to both intended use and technological characteristics.

E. Performance Data

The modifications to the Siemens ACUSON X300 Diagnostic Ultrasound System are verified and validated according to the company's design control process.

F. A brief discussion of nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence.

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform with applicable medical device safety standards. The system complies with the following voluntary standards:

UL-60601-1, Safety Requirements for Medical Equipment

IEC 60601-2-37 Diagnostic Ultrasound Safety Standards

CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment

AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound

93/42/EEC Medical Devices Directive

Safety and EMC Requirements for Medical Equipment

EN/IEC 60601-1

EN/IEC 60601-1-1

EN/IEC 60601-1-2

IEC 1157 Declaration of Acoustic Power

ISO 10993-1 Biocompatibility

Cleared patient contact materials, electrical and mechanical safety are unchanged.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Siemens Medical Solutions USA, Inc. Ultrasound Group
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JUN 22 2012

Re: K121699

Trade/Device Name: ACUSON X300™ Diagnostic Ultrasound System; SONOVISTA X 300 Diagnostic Ultrasound Systems; ACUSON X300™ Diagnostic Ultrasound System, premium edition

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX, and DQO

Dated: June 7, 2012

Received: June 8, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the ACUSON X300™ Diagnostic Ultrasound System, SONOVISTA X 300 Diagnostic Ultrasound Systems, and ACUSON X 300™ Diagnostic Ultrasound System, premium edition, as described in your premarket notification:

Transducer Model Number

P4-2 Phased Sector Array

CH5-2 Convex Array

VF10-5 Linear Array

L9-5 Linear Array

EC9-4 Convex Array

EV9-4 Convex Array

VF13-5 Linear Array

P8-4 Phased Sector Array

BE 9-4 Convex Array

CW2 Continuous Wave Doppler

CW5 Continuous Wave Doppler

AcuNav 8F Intracardiac

AcuNav 10F Intracardiac

V5Ms TEE

4V1c Phased Sector Array

VF13-5SP Linear Array

C8-5 Tightly Curved Array
8L3 Linear "Regel"
10V4 Phased Array
C7F2 Curved Array Mechanical 3D/4D
EV9F4 Curved Array Mechanical 3D/4D
L13F5 3D/4D Mechanical Wobbler Linear

VF8-3 Linear Array
P5-1 Phased Array
C6-2 Convex Array
SoundStar 10F
P9-4 Phased Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

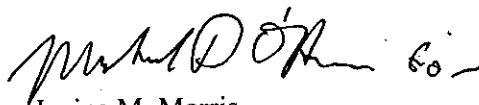
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOFFICES/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Joshua Nipper at (301) 796-6524.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

SECTION 6 Indications for Use Forms

Indications for Use Statement

510(k) Number (if known):

Device Name: ACUSON X300™ Diagnostic Ultrasound System
SONOVISTA X300 Diagnostic Ultrasound System
ACUSON X300™ Diagnostic Ultrasound System, premium edition

Indications For Use:

The Siemens Acuson X300 ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Neonatal/Adult Cephalic, Cardiac, Transesophageal, Pelvic, Transcranial, OB/GYN, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



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Office of In Vitro Diagnostic Devices

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Neuro)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-rectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
Imaging & Other	Trans-vaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-urethral										
	Trans-esoph. (non-Card.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Convent.)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
Cardiac	Trans-esophageal (Cardiac)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11

N = new indication; P = previously cleared by K080760; K090276

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

Note 10 Intracardiac imaging

Note 11 Dynamic TCE

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: P4-2 Phased Sector Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks11& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,5,6,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)										
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-rectal										
Cardiac	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic.)										
	Intra-vascular										
Peripheral Vessel	Other (Specify)										
	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
Peripheral Vessel	Intra-cardiac										
	Other (Specify)										

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 3 3D imaging

Note 5 Power SieScape panoramic imaging

Note 7 Contrast agent imaging

Note 9 Tissue Equalization Technology

Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging

Note 4 B&W SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 8 SieClear multi-view spatial compounding

Note 10 Intracardiac imaging

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: CH5-2 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic									BMDC	
Fetal	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
Imaging & Other	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superficial)										
	Intra-vascular										
	Other (Specify)										
	Cardiac Adult		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
Peripheral	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
Vessel	Other (Specify)										

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging
Note 8 SieClear multi-view spatial compounding
Note 9 Tissue Equalization Technology
Note 10 Intracardiac imaging
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: VF10-5 Linear Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Fetal Imaging & Other	Ophthalmic										
	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
Cardiac	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
Peripheral Vessel	Intra-vascular										
	Other (Specify)										
	Cardiac Adult										
	Cardiac Pediatric										
Peripheral Vessel	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
Vessel	Other (Specify)										

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: L9-5 Linear Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
Fetal Imaging & Other	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
Cardiac	Intra-vascular										
	Other (Specify)										
	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
Peripheral Vessel	Intra-Cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **EC9-4 Convex Array Transducer for use with:**
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Note 1)	P	P	P		P	P			BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic	P	P	P		P	P			BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal	P	P	P		P	P			BMDC	Note 2,3,4,5,7,8,9,11
	Trans-vaginal	P	P	P		P	P			BMDC	Note 2,3,4,5,7,8,9,11
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-Cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel										
	Other (Specify)										

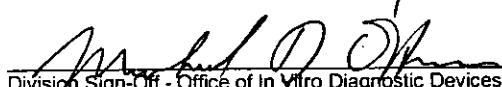
N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 3 3D imaging
- Note 5 Power SieScape panoramic imaging
- Note 7 Contrast agent imaging
- Note 9 Tissue Equalization Technology
- Note 11 Dynamic TCE

- Note 2 Ensemble tissue harmonic imaging
- Note 4 B&W SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 8 SieClear multi-view spatial compounding
- Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: EV9-4 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Note 1)	P	P	P		P	P			BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic	P	P	P		P	P			BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal	P	P	P		P	P			BMDC	Note 2,3,4,5,7,8,9,11
	Trans-vaginal	P	P	P		P	P			BMDC	Note 2,3,4,5,7,8,9,11
Cardiac	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Peripheral Vessel	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-Cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel										
	Other (Specify)										

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: VF13-5 Linear Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
Fetal	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
Imaging & Other	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

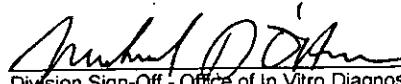
N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:
P8-4 Phased Sector Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:
Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks 1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,5,6,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)										
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superficial)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 3 3D imaging

Note 5 Power SieScape panoramic imaging

Note 7 Contrast agent imaging

Note 9 Tissue Equalization Technology

Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging

Note 4 B&W SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 8 SieClear multi-view spatial compounding

Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: BE 9-4 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks 1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Note 1)	P	P	P		P	P			BMDC	Note 2,3,4,5,7,8,9
	Neonatal Cephalic	P	P	P		P	P			BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic										
	Trans-rectal	P	P	P		P	P			BMDC	Note 2,3,4,5,7,8,9
	Trans-vaginal	P	P	P		P	P			BMDC	Note 2,3,4,5,7,8,9
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superficial)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel										
	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 3 3D imaging
- Note 5 Power SieScape panoramic imaging
- Note 7 Contrast agent imaging
- Note 9 Tissue Equalization Technology
- Note 11 Dynamic TCE

- Note 2 Ensemble tissue harmonic imaging
- Note 4 B&W SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 8 SieClear multi-view spatial compounding
- Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: CW2 Continuous Wave Doppler Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal					P					
	Abdominal					P					
	Intra-operative (Note 6)					P					
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric					P					
	Small Organ (Note 1)					P					
	Neonatal Cephalic					P					
	Adult Cephalic					P					
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)					P					
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult					P					
	Cardiac Pediatric					P					
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral	Peripheral vessel					P					
Vessel	Other (Specify)										

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **CWS Continuous Wave Doppler Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use: **Diagnostic imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal					P					
	Abdominal					P					
	Intra-operative (Note 6)					P					
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric					P					
	Small Organ (Note 1)					P					
	Neonatal Cephalic					P					
	Adult Cephalic					P					
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)					P					
	Musculo-skel. (Superfic)										
Cardiac	Intra-vascular										
	Other (Specify)										
	Cardiac Adult					P					
	Cardiac Pediatric					P					
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
Peripheral Vessel	Intra-Cardiac										
	Other (Specify)										
	Peripheral vessel					P					
	Other (Specify)										

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: AcuNav 8F Intracardiac Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks 1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
	Fetal										
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
Fetal	Pediatric	P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11	
Imaging & Other	Small Organ (Note 1)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic.)										
	Intra-vascular	P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11	
	Other (Specify)										
Cardiac	Cardiac Adult	P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11	
	Cardiac Pediatric	P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11	
	Intra-vascular (Cardiac)	P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11	
	Trans-esophageal (Cardiac)										
	Intra-cardiac	P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11	
	Other (Specify)										
Peripheral Vessel	Peripheral vessel										
	Other (Specify)										

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **AcuNav 10F Intracardiac Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use: **Diagnostic imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal										
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric	P	P	P	P	P	P			BMDC	Note 2,3,7,8,9,10,11
	Small Organ (Note 1)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
Cardiac	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superficial)										
	Intra-vascular	P	P	P	P	P	P			BMDC	Note 2,3,7,8,9,10,11
Peripheral Vessel	Other (Specify)										
	Peripheral vessel										
	Other (Specify)										

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 3 3D imaging

Note 5 Power SieScape panoramic imaging

Note 7 Contrast agent imaging

Note 9 Tissue Equalization Technology

Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging

Note 4 B&W SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 8 SieClear multi-view spatial compounding

Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: V5Ms TEE Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal										
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Note 1)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)										
Cardiac	Intra-vascular										
	Other (Specify)										
	Cardiac Adult	P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,11	
	Cardiac Pediatric	P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,11	
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)	P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,11	
Peripheral Vessel	Intra-cardiac										
	Other (Specify)										

N = new indication; P = previously cleared by K090276

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **4V1c Phased Sector Array Transducer for use with:**
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,5,6,7,8,9
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Small Organ (Note 1)										
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Trans-rectal										
Imaging & Other	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superficial)										
	Intra-vascular										
	Other (Specify)										
	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular (Cardiac)										
Peripheral Vessel	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Other (Specify)										

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 3 3D imaging

Note 5 Power SieScape panoramic imaging

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

Note 10 Intracardiac imaging

Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging

Note 4 B&W SieScape panoramic imaging

Note 6 For example: abdominal, vascular

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:
VF13-5SP Linear Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:
 Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal	Fetal										
	Abdominal										
	Intra-operative (Note 6)	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Neuro)	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Laparoscopic										
	Pediatric	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superficial)	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8,9,11
Cardiac	Intra-vascular										
	Other (Specify)										
	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
Peripheral Vessel	Intra-cardiac										
	Other (Specify)										
Peripheral	Peripheral vessel	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8,9,11
Vessel	Other (Specify)										

N = new indication; P = previously cleared by K080760

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 3 3D imaging
- Note 5 Power SieScape panoramic imaging
- Note 7 Contrast agent imaging
- Note 9 Tissue Equalization Technology
- Note 11 Dynamic TCE

- Note 2 Ensemble tissue harmonic imaging
- Note 4 B&W SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 8 SieClear multi-view spatial compounding
- Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **C8-5 Tightly Curved Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks 11 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
Fetal imaging & Other	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Musculo-skel. (Superfic)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Cardiac Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Other (Specify)										

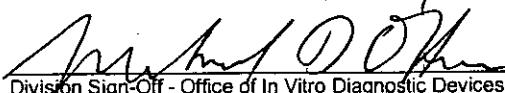
N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:
8L3 Linear "Regel" Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:
Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Musculo-skel. (Superfic.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel	P	P	P		P	P			BMDC	Note 2,3,4,5,7,8,9
	Other (Specify)										

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **10V4 Phased Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Fetal Imaging & Other	Ophthalmic										
	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Small Organ (Note 1)										
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic										
Cardiac	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Musculo-skel. (Superficial)										
Peripheral Vessel	Intra-vascular										
	Other (Specify)										
	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding.
Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: C7F2 Curved Array Mechanical 3D/4D Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
Cardiac	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)	P	P	P		P	P			BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic.)										
	Intra-vascular										
Peripheral Vessel	Other (Specify)										
	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
Other (Specify)											

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 3 3D imaging

Note 5 Power SieScape panoramic imaging

Note 7 Contrast agent imaging

Note 9 Tissue Equalization Technology

Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging

Note 4 B&W SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 8 SieClear multi-view spatial compounding

Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

EV9F4 Curved Array Mechanical 3D/4D Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
Fetal Imaging & Other	Trans-rectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-vaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic.)										
	Intra-vascular										
	Other (Specify)										
	Cardiac Adult										
	Cardiac Pediatric										
Cardiac	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
	Peripheral vessel										
Peripheral Vessel	Other (Specify)										

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: L13F5 3D/4D Mechanical Wobbler Linear Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Musculo-skel. (Superficial)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Other (Specify)										

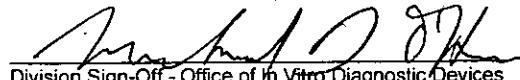
N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF8-3 Linear Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
Fetal	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
Imaging & Other	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superficial)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
Vessel	Other (Specify)										

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: P5-1 Phased Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)										
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic.)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **C6-2 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks 1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)										
	Neonatal Cephalic										
	Adult Cephalic										
Fetal Imaging & Other	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic.)										
	Intra-vascular										
	Other (Specify)										
	Cardiac Adult		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
Cardiac	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										
Peripheral Vessel											

N = new indication; P = previously cleared by K080760

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: SoundStar 10F Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal imaging & Other	Fetal										
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Note 1)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
Cardiac	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)										
	Intra-vascular	P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11	
	Other (Specify)										
	Cardiac Adult	P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11	
	Cardiac Pediatric	P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11	
	Intra-vascular (Cardiac)	P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11	
Peripheral Vessel	Trans-esophageal (Cardiac)										
	Intra-cardiac	P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11	
Peripheral Vessel	Other (Specify)										
	Peripheral vessel										
Peripheral Vessel	Other (Specify)										

N = new indication; P = previously cleared by K080760;

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:
P9-4 Phased Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
	Fetal	N	N	N	N	N	N	N		BMDC	
	Abdominal	N	N	N	N	N	N	N		BMDC	
	Intra-operative (Note 6)										
	Intra-operative (Neuro)	N	N	N		N	N			BMDC	
	Laparoscopic										
	Pediatric	N	N	N	N	N	N	N		BMDC	
	Small Organ (Note 1)	N	N	N	N	N	N	N		BMDC	
	Neonatal Cephalic	N	N	N	N	N	N	N		BMDC	
	Adult Cephalic	N	N	N	N	N	N	N		BMDC	
Fetal Imaging & Other	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superficial)										
	Intra-vascular										
	Other (Specify)										
	Cardiac Adult	N	N	N	N	N	N	N		BMDC	
	Cardiac Pediatric	N	N	N	N	N	N	N		BMDC	
Cardiac	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Cardiac Neonatal)	N	N	N	N	N	N	N		BMDC	
	Peripheral vessel	N	N	N	N	N	N	N		BMDC	
Vessel	Other (Specify)										

N = new indication; P = previously cleared by FDA K090276

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging

Note 5 Power SieScape panoramic imaging

Note 7 Contrast agent imaging

Note 9 Tissue Equalization Technology

Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging

Note 4 B&W SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 8 SieClear multi-view spatial compounding

Note 10 Intracardiac imaging

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